



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

#15
Election
6.19.03

Application of : SCHUBART et al.
Serial No. : 09/981,397
Filed : October 16, 2001
Entitled : CELLULAR KINASES INVOLVED IN
CYTOMEGALOVIRUS INFECTION AND
THEIR INHIBITION

ART UNIT: 1648

EXAMINER: SALIMI, A.R.

Atty. Docket No.: AXM-004.1 US

Commissioner for Patents
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Alexandria, VA 22313-1450

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RESPONSE TO RESTRICTION REQUIREMENT

Sir:

This paper is filed in response to the Office Action dated March 11, 2003. A petition for a two-month extension of time is also submitted herewith, making the new response date June 11, 2003.

In the Office Action, a restriction of Applicants' invention has been required, as between:

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| Group I | (Claims 1, 20 and 21) drawn to methods of identifying CMV-related protein kinase inhibitors and solid support useful in screening for such compounds; |
| Group II | (Claims 2, 18 and 25) drawn to methods of detecting CMV infection in individuals; |
| Group III | (Claims 3, 19 and 25) drawn to methods of detecting CMV in cell lysates; |
| Group IV | (Claims 4-8) drawn to antibodies that bind CMV-related protein kinases and therapeutic uses therefor; |
| Group V | (Claims 5-7, 13, 14 and 15) drawn to CMV prophylactic/therapeutic treatments utilizing oligonucleotides as inhibitors; |
| Group VI | (Claims 9-11, 16-17, and 25) drawn to CMV prophylactic/therapeutic treatments utilizing activators for the CMV-related kinases; |

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| Group VII | (Claim 12) drawn to oligonucleotides that bind DNA/RNA encoding the CMV-related kinases; |
| Group VIII | (Claim 22) drawn to compositions with inhibitors useful in therapeutically treating CMV-infected individuals; |
| Group IX | (Claim 23) drawn to compositions with activators useful in therapeutically treating CMV-infected individuals; and |
| Group X | (Claims 24, 26-28) drawn to particular compositions useful for the prophylactic/therapeutic treatment of CMV-infected individuals. |

The Examiner reasons as follows:

"Inventions of Groups I-X are mutually exclusive and patentably distinct products and methods which each are structurally and functionally different products and methods and are substantially different. The products are made by different methods, and multiple methods have different uses and delineate different results, and have different effect on interaction, antigenicity and/or immune response. The structures of various kinases, oligonucleotides, activators, inhibitors, or antibodies and their functionalities are different. The Examination of all groups would require different searches in the U.S. Patent Shoes and scientific literature and would require the consideration of different patentability issues. (Office Action, page 5.)

In addition to imposing a ten-way restriction, the Examiner requires further election of a single sequence, kinase, activator, inhibitor, compound, or antibody for the invention group selected.

Applicants traverse this requirement and request consideration of all claims together in this application, or at least a re-grouping of the restriction, for the reasons set forth below.

The present invention relates to the discovery that particular cellular protein kinases (RICK, RIP, NIK, MKK3, and SPRK-2) are specifically and uniquely upregulated in a cell as a result of CMV infection. Methods and prophylactic/therapeutic compounds that flow naturally from such discovery are disclosed and claimed.

The Examiner's original grouping of the claims indicates that each of the practical applications of the above discovery described in the application and recited in the claims have been regarded as a separate invention that must be prosecuted separately, as has every use of the compounds discovered to treat CMV as defined in the claims. However, because the embodiments of the invention share common features, fractionation of the claims as required in the Office Action would lead to unnecessarily

repetitive examination and an unfairly protracted and expensive series of related applications to be filed by Applicants to obtain the patent protection to which they are entitled. Moreover, they are not unrelated methods and products; they are all methods and products that stem from the link discovered between the upregulation of RICK, RIP, NIK, MKK3, and SPRK-2, in CMV infection.

In view of these common features, it is seen that all of the methods and accompanying compounds recited in the claims may be efficiently searched together, without placing an undue burden on the Examiner.

In the Office Action, the Examiner asserts that the present application contains distinct inventions that have acquired a separate status in the art, as shown by their different classification. Applicants disagree. Proper restriction between distinct inventions claimed in the same application requires (1) that the inventions must be independent and distinct as claimed *and* (2) that there must be a serious burden placed on the Examiner by *not* requiring restriction. If either criterion is not met, restriction is not proper. MPEP §803.

Applicants note that Groups I-III, V, and VI of the present invention are provisionally classified in one class, i.e. Class 435. In the present case the subject matter of the original claims cannot properly be divided into distinct inventions due to the interrelatedness of the subject matter as claimed. Additionally, the claims are of the type that may be examined together pursuant to 37 CFR §1.141(b). Finally, in view of the initial classification and the way in which the claims are worded, Applicants submit that the search of any of the method claim groups, Groups I-III, V, and VI, would reveal the same art that is relevant to the other groups, and therefore no serious burden is on the Examiner if a restriction is not made. Instead, the burden will be on the Applicants, who will be required to increase their expenses to address the same search before full patent protection of their original invention is obtained.

Applicants note that Groups II and III, in particular, are logically interrelated, as the only difference between Claims 2 and 3 is the sample; the CMV-infection detection steps are identical.

Conclusion and Provisional Election

Applicants submit that in view of the foregoing remarks all the claims as originally filed are seen to relate to a single inventive concept, and the claims are in a form and are of the sort that is properly viewed as relating to a single invention that should not be restricted. Applicants request that the restriction requirement of the Office Action of March 11, 2003 be reconsidered and withdrawn.

Although, for reasons set forth above, Applicants believe that the restriction is improper and uncalled for, and without in any way acquiescing in the reasons for the requirements set forth in the

Office Action, but in order to be fully responsive to the Office Action, Applicants provisionally elect for examination the claims of Group I, i.e., Claims 1, 20 and 21. Applicants further provisionally elect RIP protein kinase (SEQ ID NO: 16) for search.

Respectfully submitted,



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Stephanie Leicht
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